Monitoring of the Lenalidomide Pregnancy Prevention Programme (PPP) Implementation and Effectiveness in Germany (Lena-PIE Germany)

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Study Ongoing

Administrative details

EU PAS number

EUPAS45747

Study ID

45853

DARWIN EU® study

No

Study countries

☐ Germany

Study description

Evaluation of the outcome indicator (safety outcome): (i) Immediate follow-up and root-cause analysis of all pregnancy cases in association with an exposition to Lenalidomid AL Hartkapseln or Lenalidomid STADA Hartkapseln in Germany reported to STADA. (ii) Systematic database review in STADA's safety database to ensure that no pregnancy case in association with an exposition to Lenalidomid AL Hartkapseln or Lenalidomid STADA Hartkapseln in Germany was missed. Follow-up and root-cause analysis of missed cases. (iii) Systematic review of EudraVigilance data to identify pregnancy cases in association with an exposition to Lenalidomid AL Hartkapseln or Lenalidomid STADA Hartkapseln in Germany not known to STADA. Data entry and processing in STADA's safety database, follow-up and root-cause analysis of cases not known.

Study status

Ongoing

Research institutions and networks

Institutions

STADA Arzneimittel

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Institution

Contact details

Study institution contact

Sonja Gomez Perez Sonja.Gomez-Perez@stada.de

Study contact

Sonja.Gomez-Perez@stada.de

Primary lead investigator

Markus Torben Schweimer

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 06/01/2022

Actual: 06/01/2022

Study start date

Planned: 18/02/2022

Actual: 18/02/2022

Data analysis start date

Planned: 18/02/2027

Date of final study report

Planned: 18/02/2028

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

STADA Arzneimittel AG

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

Other study registration identification numbers and links

STADA study code: PASS-37480-21-0245

Methodological aspects

Study type

Study type list

Study type:

Not applicable

Main study objective:

The objectives of this study are to identify and follow-up on all pregnancies which occur in association with an exposition to Lenalidomid AL Hartkapseln or Lenalidomid STADA Hartkapseln in Germany, to perform a root-cause analysis for such identified cases, and to identify causes that could indicate a failure or weakness of the PPP.

Study drug and medical condition

Name of medicine, other

Lenalidomid AL 2,5 / 5 / 7,5 / 10 / 15 / 20 / 25 mg Hartkapseln, Lenalidomid STADA 2,5 / 5 / 7,5 / 10 / 15 / 20 / 25 mg Hartkapseln

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Medical condition to be studied

Exposure during pregnancy

Population studied

Age groups

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Special population of interest

Pregnant women

Estimated number of subjects

0

Study design details

Outcomes

(i) Pregnancy in female patient: conception up to 4 weeks after lenalidomide exposition in female patient, (ii) Pregnancy in female partner of male patient: conception up to 7 days after lenalidomide exposition in male patient.

Data analysis plan

Data analysis will be performed as follows: (i) Single case analysis of all pregnancy cases in association with an exposition to Lenalidomid AL Hartkapseln or Lenalidomid STADA Hartkapseln in Germany reported to or identified by STADA, (ii) Descriptive statistics for summarizing data from pregnancy cases in association with an exposition to Lenalidomid AL Hartkapseln or Lenalidomid STADA Hartkapseln.

Data management

Data sources

Data sources (types)

Other

Spontaneous reports of suspected adverse drug reactions

Data sources (types), other

Systematic database review

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No